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10/542,646	07/19/2005	Johannes Fridolin Schlapfer	8932-1208-999	1676

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/542,646

Applicant(s)

SCHLAPFER ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 12, third full paragraph; page 14, paragraph 7 beginning "Accordingly..." and the following paragraph; filed 11/28/2006 with respect to the rejection(s) of claim(s) 1-18 under 35 USC § 102(b) and 35 USC § 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Saurat (US Pat. 6,099,528) and Kahn et al. (US Pat. 3,938,198).

Claim Objections

Claims 1-23 are objected to because of the following informalities:

In claim 1, lines 4-5, it appears --is-- should be inserted between "support" and "plastically". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "encasing" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the bone-anchoring means" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Saurat (US Pat. 6,099,528).

Saurat disclose an apparatus for the dynamic stabilization of bones or bone fragments, in particular spinal vertebrae, comprising a longitudinal support (Fig. 9, ref. 25) that can be fixed to the vertebra, the longitudinal support is plastically deformable from a first stable shape state into a second stable shape state by application of a prespecified bending force, the longitudinal support remaining flexible within predetermined limits while in the first and second stable shape states. The longitudinal support is elastically deflectable when clamped at one end while in the first or second stable shape states. With regards to the statement that the rod is elastically deflectable, the longitudinal support has a varying stiffness across the support (column 1, lines 36-38), which implies that at least portions of the rod are flexible (*i.e.* less stiff). Since the rod is flexible, it is elastically deformable. The longitudinal support is stable and unyielding with respect to anatomically usual longitudinal shear forces and with respect

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to anatomically usual transverse shear forces. The longitudinal support is substantially stable when subjected to anatomically usual torsion. The longitudinal support is in the shape of a flat band or strip. The definition of "strip" according to The Merriam-Webster Online Dictionary is "a long narrow piece of material." The longitudinal support of Saurat is a long narrow piece of material, as seen in Fig. 9, ref. 25. The longitudinal support is rotationally symmetrical (Fig. 3). The longitudinal support is hollow (column 4, lines 64-66). The longitudinal support comprises a plastically deformable core made of metal (Fig. 9, ref. 26) (column 3, lines 63-65) encased in a human-tissue-compatible plastic (column 3, lines 65-67 and column 4, lines 1-2) that provides flexibility within a stable shape state. The longitudinal support is dimensioned such that within the predetermined limits its surface stress is always below the dynamic breaking stress. The core and the plastic encasing is always below the respective dynamic breaking stress. The core is encased in more than one layer (column 5, lines 3-5). The longitudinal support can be fixed. The apparatus further comprises longitudinal support-connecting-means, operative to connect at least two support sections to one another (column 4, lines 24-30). The longitudinal-support-connecting means comprising two oppositely situated support-receiving openings (Fig. 12, openings near ref. 35 and ref. 36) into each of which an end section of the support (Fig. 12, ref. 35 and 36) can be inserted (Fig. 12) and fixed by a clamping screw or similar clamping element (Fig. 12, ref. 34) (column 4, lines 24-31). The bone anchoring means (Fig. 13, ref. 37) comprise longitudinal-support-receiving openings (Fig. 13, openings in refs. 37, top and bottom, through which ref. 19 passes) that can be spaced at variable axial distances from the opposite distal

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end, so that the longitudinal support can be adjusted to a correspondingly different distance from the vertebra. The core is in the form of a flat band or strip, with a width smaller than or equal to the corresponding dimension of the longitudinal support (Figs. 3, 4, and 5, refs. 6, 8, and 11). The core can be considered to be a strip since it is a long narrow piece of material (Fig. 9, ref. 26). The core is rotationally symmetrical (Fig. 3, ref. 6), with either a constant diameter or a diameter that varies along the length of the longitudinal support (column 2, lines 43-55). The diameter of the core, at least in sections, is continually enlarged or reduced and/or altered in a stepwise manner (column 2, lines 43-55) (Fig. 1, step near where ref. 2 points), the transitions of the stepwise manner in the region of a step are constructed so as to reduce stress. The transitions of the stepwise manner in the region of a step are rounded (since the core can be round, e.g. Fig. 3, ref. 6) to reduce stress. The rotationally symmetrical core is circular (Fig. 3, ref. 6). The longitudinal support comprises a hollow rod (column 2, lines 43-47). The predetermined limits comprise the elastic flexion range.

With regards to statements of intended use and other functional statements (e.g. "...can be fixed to the vertebra...", "...plastically deformable from a first stable shape state into a second stable shape state by application of a prespecified bending force...", "...remaining flexible within predetermined limits while in the first and second stable shape states...", "...provides flexibility within a stable shape state...", "...the longitudinal support is stable and unyielding...", "...its surface stress is always below the dynamic breaking stress...", "...can be fixed...", "...operative to connect..." etc.), they do not impose any structural limitations on the claims distinguishable over the device of Saurat,

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which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saurat (US Pat. 6,099,528).

With regards to claim 2, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the elastically deflectable longitudinal support of Saurat with the rod being elastically deflecatable by an angle of 5 to 12 degrees, over a length corresponding to the spacing of two adjacent vertebrae, or about 2 to 5 cm, since it has been held that where the general conditions

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of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saurat (US Pat. 6,099,528) in view of Kahn et al. (US Pat. 3,938,198).

Saurat discloses the claimed invention except for the metal core comprising titanium or a titanium alloy.

Kahn et al. disclose a rod (Fig. 1, ref. 13) with a metal core (column 2, lines 52-55) comprising titanium (column 2, lines 52-55) surrounded by a different material (column 2, lines 44-52), the core being made out of titanium in order to provide a core which is strong, lightweight, and resistant to attack by body fluids (Kahn et al., column 2, lines 52-55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have made the core of Saurat from titanium as taught by Kahn et al, in order to provide a core which is strong, lightweight, and resistant to attack by body fluids (Kahn et al., column 2, lines 52-55).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571)

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272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER